Food and Drug Administration

466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

WARNING LETTER
SJN-01-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 20, 2000

Gerardo Latoni, M.D.
Medical Director
Banco de Sangre Humacao, Inc.
P.O. Box 9121
Humacao, PR 00971

Dear Dr. Latoni:

From November 14 to 28, 2000 an investigator from our office conducted an inspection of your unlicensed hospital blood bank located at 255 Font Martello St., Humacao, PR. The investigator documented deviations from the Current Good Manufactuing Practices (GMP's) for Blood and Components, Title 21, Code of Federal Regulations, part 606 (21 CFR 606) and Additional Standards for Human Blood and Blood Products (21 CFR 640). These deviations cause the Blood and Blood products manufactured and tested by your firm to be adulterated within the meaning of section 501 (a) (2) (b) of the Food Drug and Cosmetic Act (the Act).

The deviations reported were as follows:

1. Failure to maintain accurate records that are completed concurrently with the performance of each significant step in the collection of blood and blood products in accordance with 21 CFR 606.160 (a)(1). For example:

   Information required for the physical examination that was not obtained during screening of the donor for unit H11686 was entered into the donor record after he left the firm.

2. Failure to perform adequate screening of donors for health problems or medications which could affect the quality of blood products for transfusion, in accordance with 21 CFR 640.3. For example:

   Donor # H11686 reported during the screening process that within the previous 24 hours he had ingested an unspecified amount of naproxen sodium due to an unspecified illness.

Naproxen sodium is included in your firm's donor screening drug list with the notation that it is unsuitable for platelet donation if more than one dose is taken in the previous 24 hours. In addition, the donor reported that the donation was being made for therapeutic reasons. No further questions were asked of the donor to determine the dosage of medication taken or the nature of the donor's illness. The donation from this individual was processed into platelet concentrate and was not labeled as a therapeutic donation.

3. Laboratory controls do not include adequate provisions for monitoring the reliability, accuracy and precision of test procedures as required by 21 CFR 606.140 (b). For example:

   The procedure for receiving viral marker test results from the contract testing laboratory does not include any steps for review and evaluation of the testing practices of the contract laboratory to assure they conform to test kit instructions or any requirements for evaluating aberrant test results.

The above identified deviations are not intended to be an all-inclusive list if deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the address on the letterhead above to the attention of Mary L. Mason, Compliance Officer.

Sincerely,

Wayne Matthews for
Mildred R. Barber
District Director